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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

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Total Number of Pages in This Submission

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Application Number

10/091,744

Filing Date

March 5, 2002

First Named Inventor

Holman, Andrew

Group Art Unit

1614

Examiner Name

Unassigned

Attorney Docket Number

020862-000110US

ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Fee Attached

☐ Amendment / Response

☐ After Final

☐ Affidavits/declaration(s)

☐ Extension of Time Request

☐ Express Abandonment Request

☒ Information Disclosure Statement

☐ Certified Copy of Priority Document(s)

☐ Response to Missing Parts/
Incomplete Application

☐ Response to Missing
Parts under 37 CFR
1.52 or 1.53

☐ Assignment Papers
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition Routing Slip (PTO/SB/69)
and Accompanying Petition

☐ Petition to Convert to a
Provisional Application

☐ Power of Attorney, Revocation
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s)

☐ After Allowance Communication to
Group

☐ Appeal Communication to Board of
Appeals and Interferences

☐ Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s)
(please identify below):

Form PTO-1449; References AA-DY;
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Remarks

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Firm
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Individual name

Townsend and Townsend and Crew LLP
Mark G. Sandbaken, Ph.D.

Reg. No. 39,354

Signature

Mark G. Sandbaken

Date

August 9, 2002.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

ANDREW HOLMAN

Application No.: 10/091,744

Filed: March 5, 2002

For: ADMINISTRATION OF SLEEP
RESTORATIVE AGENTS

Examiner: Unassigned

Art Unit: 1614

**INFORMATION DISCLOSURE
STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants direct the Examiner's attention to the references below, also listed on the accompanying Form PTO-1449. A copy of each is also enclosed.

The following U.S. Patents are set forth below by issue date:

- AA. U.S. Patent No. 4,452,808, issued June 5, 1984 to Gallagher, Jr.
- AB. U.S. Patent No. 4,843,086, issued June 27, 1989 to Griss, deceased *et al.*
- AC. U.S. Patent No. 4,886,812, issued Dec. 12, 1989 to Griss, deceased *et al.*
- AD. U.S. Patent No. 5,112,842, issued May 12, 1992 to Zierenberg *et al.*
- AE. U.S. Patent No. 5,650,420, issued Jul. 22, 1997 to Hall *et al.*
- AF. U.S. Patent No. 5,658,955, issued Aug. 19, 1997 to Hitzig.
- AG. U.S. Patent No. 5,694,950 issued Dec. 9, 1997 to McMichael.
- AH. U.S. Patent No. 5,696,128, issued Dec. 9, 1997 to Cincotta *et al.*
- AI. U.S. Patent No. 5,786,344 issued July 28, 1998 to Ratain *et al.*
- AJ. U.S. Patent No. 5,842,997, issued Dec. 1, 1998 to Verrier *et al.*

AK. U.S. Patent No. 5,843,943 issued Dec. 1, 1998 to Carson *et al.*
AL. U.S. Patent No. 5,872,127, issued Feb. 16, 1999 to Cincotta *et al.*
AM. U.S. Patent No. 5,872,133, issued Feb. 16, 1999 to Cincotta *et al.*
AN. U.S. Patent No. 5,905,083, issued May 18, 1999 to Cincotta *et al.*
AO. U.S. Patent No. 5,921,940, issued Jul. 13, 1999 to Verrier *et al.*
AP. U.S. Patent No. 5,932,252, issued Aug. 3, 1999 to Morris Jr. *et al.*
AQ. U.S. Patent No. 5,952,389, issued Sept. 14, 1999 to Fogel.
AR. U.S. Patent No. 6,001,861, issued Dec. 14, 1999 Oertel *et al.*
AS. U.S. Patent No. 6,057,373, issued May 2, 2000 to Fogel.
AT. U.S. Patent No. 6,156,777, issued Dec. 5, 2000 to Hall *et al.*
AU. U.S. Patent No. 6,191,153, issued Feb. 20, 2001 to Hammer *et al.*
AV. U.S. Patent No. 6,194,445, issued Feb. 27, 2001 to Oertel *et al.*
AW. U.S. Patent No. 6,204,245 issued Mar. 20, 2001 to Siegel *et al.*
AX. U.S. Patent No. 6,255,329, issued July 3, 2001 to Maj.
AY. U.S. Patent No. 6,258,827, issued July 10, 2001 to Chenard *et al.*
AZ. U.S. Patent No. 6,277,875, issued Aug. 21, 2001 to Holman.
BA. U.S. Patent No. 6,294,583, issued Sept. 25, 2001 to Fogel.
BB. U.S. Patent No. 6,300,365, issued Oct. 9, 2001 to Holman.

The following articles are set forth in alphabetical order:

BC. Aksoyek *et al.*, "Assessment of autonomic nervous system function in patients with Behcet's disease by spectral analysis of heart rate variability," *J. Auton. Nerv. Syst.* 77(2-3):190-4 (Sept. 24, 1999).

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BU. Lagos *et al.*, "Effects of the D₃ preferring dopamine agonist pramipexole on sleep and waking, locomotor activity and striatal dopamine release in rats," *Eur. Neuropsychopharmacol.* 8(2):113-20 (May 1998).

BV. Lam, "Clinical pharmacology of dopamine agonists," *Pharmacotherapy* 20(1 Pt. 2): 17S-25S (2000).

BW. Leanos Miranda *et al.*, "Prolactin as an immunomodulator," *Rev. Alerg. Mex.* 44(5):116-23 (Sept-Oct., 1997).

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CW. Sinoway, "Direct Assessment of Sympathetic Neural Activity in Patients with Heart Failure During Exercise," Abstract from Research Workshop entitled "Effect of Acupuncture on Cardiovascular Disease, Its Mechanism and Clinical Application", University of California at Irvine (Oct. 14-15, 2000).

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CY. Sun *et al.*, "Iron and the restless legs syndrome," *Sleep* 21(4):371-7 (1998).

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DE. Wolfe *et al.*, "The American College of Rheumatology 1990 - Criteria for the classification of the fibromyalgia, Report of the Multicenter Criteria Committee," *Arthritis and Rheumatism* 33(2):160-72 (Feb. 1990).

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DN. The Merck Index (Twelfth Edition), p. 1321, No. 7885, Pramipexole (1996).

DO. The Merck Index (Twelfth Edition), p. 1421, No. 8416, Ropinirole (1996).

DP. The Merck Index (Twelfth Edition), p. 1618, No. 9624, Tizanidine (1996).

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DS. Ambien (Zolpidem Tartrate) - "What time is it? It's time to say "Good Night" - Internet website: <http://www.ambien.com> (printed Mar. 5, 2001).

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DW. Searle Ambien (zolpidem tartrate) - Internet website: <http://www.searlehealthnet.com> (printed Mar. 5, 2001).

DX. Healthcare Professionals, Introduction - "Eat Less - The point of change program encourages your patients to do more" - Internet website: <http://www.4meridia.com> (printed Mar. 5, 2001).

DY. Healthcare Professionals, Mechanism of Action - "Lose weight by eating less" - Internet website: <http://www.4meridia.com> (printed Mar. 5, 2001).

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.


Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. However, Applicants reserve the right to demonstrate that their claimed invention was made prior to any one or more of the above-identified references. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

Applicants respectfully request that the Examiner review the foregoing references to make his own determination of the patentability of the present invention and that the references be made of record in the file of this application.

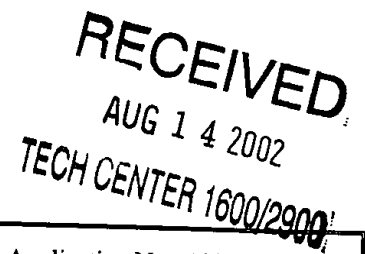
Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Dated: 8/9/02

By: 
Mark G. Sandbaken, Ph.D.
Reg. No. 39,354

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111
(206) 467-9600



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FORM PATENT (Modified)		Attorney Docket No.: 020862-000110US	Application No.: 10/091,744
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: ANDREW HOLMAN	
		Filing Date: March 5, 2002	
Reference Designation		Group: 1614	

U.S. PATENT DOCUMENTS							
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Page 1 of 1	
						Filing Date (If Appropriate)	
	AA	4,452,808	6/5/84	Gallagher, Jr.			
	AB	4,843,086	6/27/89	Griss deceased <i>et al.</i>			
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	AP	5,932,252	8/3/99	Morris Jr. <i>et al.</i>			
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)



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FORM PTO-100 (Modified)

Attorney Docket No.: 020862-000110US

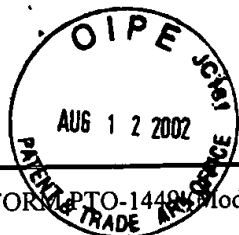
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Applicant: ANDREW HOLMAN

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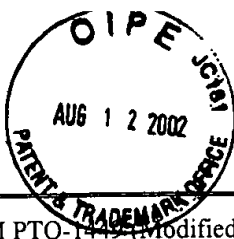
BC	Aksoyek <i>et al.</i> , "Assessment of autonomic nervous system function in patients with Behcet's disease by spectral analysis of heart rate variability," <i>J. Auton. Nerv. Syst.</i> 77(2-3):190-4 (Sept. 24, 1999).
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BW	Leanos Miranda <i>et al.</i> , "Prolactin as an immunomodulator," <i>Rev. Alerg. Mex.</i> 44(5):116-23 (Sept-Oct., 1997).
BX	Lechin <i>et al.</i> , "Plasma neurotransmitters and cortisol in chronic illness: role of stress," <i>J. Med.</i> 25(3-4): 181-92 (1994).
BY	Lieberman, "Management of Patients With Newly Diagnosed PD," Published in <i>Young Parkinson's Handbook</i> , Chapter 3: The Medical Management of PD, http://spauldingrehab.mgh.harvard.edu (printed Nov. 19, 2001).



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FORM PTO-1449 (Modified)		Attorney Docket No.: 020862-000110US	Application No. 02/1600/2900
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: ANDREW HOLMAN	
		Filing Date: March 5, 2002	Group: 1614
BZ	Lin <i>et al.</i> , "Effect of pramipexole in treatment of resistant restless legs syndrome," <i>Mayo Clin. Proc.</i> 73(6):497-500 (Jun. 1998).		
CA	Lorenc-Koci and Wolfarth, "Efficacy of pramipexole, a new dopamine receptor agonist, to relieve the Parkinsonian-like muscle rigidity in rats," <i>Eur. J. Pharmacol.</i> 385(1):39-46 (1999).		
CB	Luchsinger <i>et al.</i> , "Comparative effects of dopaminergic agonists on cardiovascular, renal, and renin-angiotensin systems in hypertensive patients," <i>J. Clin. Pharmacol.</i> 32(1):55-60 (1992).		
CC	Mader, "Bromocriptine for refractory rheumatoid arthritis," <i>Harefuah</i> 133(11):527-9, 591 (Dec. 1, 1997).		
CD	Maj <i>et al.</i> , "Antidepressant effects of pramipexole, a novel dopamine receptor agonist," <i>J. Neural. Transm.</i> 104: 4-5, 525-33 (1997).		
CE	Maj <i>et al.</i> , "The effect of repeated treatment with pramipexole on the central dopamine D ₃ system," <i>J. Neural. Transm.</i> 107(12): 1369-79 (2000).		
CF	Mannelli <i>et al.</i> , "In Vivo Evidence That Endogenous Dopamine Modulates Sympathetic Activity in Man," <i>Hypertension</i> 34:398-402 (1999).		
CG	Mannelli <i>et al.</i> , "Dopamine and sympathoadrenal activity in man," <i>Clin. Exp. Hypertens.</i> 19(1-2):163-79 (1997).		
CH	Martinez-Lavin <i>et al.</i> , "Circadian studies of autonomic nervous balance in patients with fibromyalgia," <i>Arthritis & Rheumatism</i> 41:1966-71 (Nov. 1998).		
CI	Mehta <i>et al.</i> , "Heart rate variability in healthy newborn infants," <i>Am. J. Cardiol.</i> 89(1):50-3 (Jan. 1, 2002).		
CJ	Mohler <i>et al.</i> , "Pramipexole in the treatment of advanced Parkinson's disease," <i>Eur. J. Neurology Suppl.</i> (Suppl. 1):21-25 (2000).		
CK	Mohler <i>et al.</i> , "Soluble Tumor Necrosis Factor (TNF) Receptors Are Effective Therapeutic Agents in Lethal Endotoxemia and Function Simultaneously as Both TNF Carriers and TNF Antagonists," <i>J. Immunol.</i> 151:1548-1561 (Aug. 1, 1993).		
CL	Monti and Monti, "Role of dorsal raphe nucleus serotonin 5-HT _{1A} receptor in the regulation of REM sleep," <i>Life Sci.</i> 66(21):1999-2012 (2000).		
CM	Montplaisir <i>et al.</i> , "Restless legs syndrome improved by pramipexole: a double-blind randomized trial," <i>Neurology</i> 52(5):938-43 (1999).		
CN	Montplaisir <i>et al.</i> , "Pramipexole in the treatment of restless legs syndrome: a follow-up study," <i>Eur. J. Neurol.</i> 7 Suppl. 1:27-31 (May 2000).		
CO	Orr <i>et al.</i> , "Autonomic regulation of cardiac function during sleep in patients with irritable bowel syndrome," <i>Am. J. Gastroenterol.</i> 95(10): 2865-71 (2000).		
CP	Penzel <i>et al.</i> , "Heart rate variability during sleep stages in normals and in patients with sleep apnea," <i>Stud. Health Technol. Inform.</i> 77:1256-60 (2000).		
CQ	Prescott (ed.), "Lipid Vesicles as Carriers for Introducing Biologically Active Materials into Cells," <i>Methods in Cell Biology</i> , Volume XIV, Ch. 4, Academic Press, New York, N.Y. (1976).		
CR	Quinn <i>et al.</i> , "Painful Parkinson's Disease," <i>Lancet</i> 1(8494):1366-9 (Jun. 14, 1986).		
CS	Renzetti and Gater, "Ro 45-2081, a TNF receptor fusion protein, prevents inflammatory responses in the airways," <i>Inflamm. Res.</i> 46(2):S143-S144 (1997).		
CT	Schilling <i>et al.</i> , "Neuroendocrine and side effect profile of pramipexole, a new dopamine receptor agonist, in humans," <i>Clin. Pharmacol. Ther.</i> 51(5):541-8 (May 1992).		
CU	Sears, "The evolution of β_2 -agonists," <i>Respir. Med.</i> 95(B): S2-6 (Aug. 2001).		
CV	Silber, "Concise review for Primary-Care Physicians: Restless legs syndrome," <i>Mayo Clin. Proc.</i> 72(3):261-4 (Mar. 1997).		



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FORM PTO-1449 (modified)		Attorney Docket No.: 020862-000110US	Application No.: 10/091,744
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: ANDREW HOLMAN	
		Filing Date: March 5, 2002	Group: 1614
CW	Sinoway, "Direct Assessment of Sympathetic Neural Activity in Patients with Heart Failure During Exercise," Abstract from Research Workshop entitled "Effect of Acupuncture on Cardiovascular Disease, Its Mechanism and Clinical Application", University of California at Irvine (Oct. 14-15, 2000).		
CX	Sjolin and Trykker, "Unsuccessful treatment of severe pain from bone metastasis with Sinemet 25/100," <i>N. Engl. J. Med.</i> 312(10):650-1 (Mar. 7, 1985).		
CY	Sun <i>et al.</i> , "Iron and the restless legs syndrome," <i>Sleep</i> 21(4):371-7 (1998).		
CZ	Trenkwalder <i>et al.</i> , "Periodic limb movements and restless legs syndrome," <i>Neurol. Clin.</i> 14(3):629-50 (Aug. 1996).		
DA	Tsuru <i>et al.</i> , Forum Minireview - Pharmacology and Physiology of Perivascular Nerves Regulating Vascular Function: "Role of perivascular sympathetic nerves and regional differences in the features of sympathetic innervation of the vascular system," <i>Jpn. J. Pharmacol.</i> 88(1):9-13 (2002).		
DB	Velasco and Luchsinger, "Dopamine: pharmacologic and therapeutic aspects," <i>Am. J. Ther.</i> 5(1):37-43 (1998).		
DC	Weimerskirch and Ernst, "Newer dopamine agonists in the treatment of restless legs syndrome," <i>Ann. Pharmacother.</i> 35:627-30 (May 2001).		
DD	Winkelman <i>et al.</i> , "Restless legs syndrome in end-stage renal disease," <i>Am J. Kidney Dis.</i> 28(3):372-378 (Sept. 1996).		
DE	Wolfe <i>et al.</i> , "The American College of Rheumatology 1990 - Criteria for the classification of the fibromyalgia, Report of the Multicenter Criteria Committee," <i>Arthritis and Rheumatism</i> 33(2):160-72 (Feb. 1990).		
DF	Yan and Zhang, "Analysis of heart rate variability and its application," <i>Space Med. Med. Eng.</i> 10(5):318-22 (Oct. 1997).		
DG	Zhang <i>et al.</i> , "Change in heart rate dynamics after aerobic training detected by approximate entropy and its association with orthostasis," <i>J. Gravit. Physiol.</i> 4(2):P-47 - P-48 (Jul. 1997).		
DH	The Merck Index (Twelfth Edition), p. 301, No. 1889, Carisoprodol (1996).		
DI	The Merck Index (Twelfth Edition), p. 404, No. 2449, Clonazempman (1996).		
DJ	The Merck Index (Twelfth Edition), p. 733, No. 4343, Gabapentin (1996).		
DK	The Merck Index (Twelfth Edition), p. 953, No. 5609, Lorazepam (1996).		
DL	The Merck Index (Twelfth Edition), p. 991, No. 5857, Melatonin (1996).		
DM	The Merck Index (Twelfth Edition), p. 1232, No. 7304, Pergolide (1996).		
DN	The Merck Index (Twelfth Edition), p. 1321, No. 7885, Pramipexole (1996).		
DO	The Merck Index (Twelfth Edition), p. 1421, No. 8416, Ropinirole (1996).		
DP	The Merck Index (Twelfth Edition), p. 1618, No. 9624, Tizanidine (1996).		
DQ	The Merck Index (Twelfth Edition), p. 1634, No. 9712, Trazodone (1996).		
DR	Enbrel (etanercept), issued 01/2001 - Internet website: Immunex.		
DS	Ambien (Zolpidem Tartrate) - "What time is it? It's time to say "Good Night" - Internet website: http://www.ambien.com (printed Mar. 5, 2001).		
DT	Heart rate and blood pressure variability - Internet website: http://www.nymc.edu (printed Feb. 26, 2002).		
DU	Remicade - Drug Database - Internet website: http://pharminfo.com (printed Feb. 24, 2001).		
DV	Sonata Zalepln capsules, Clinical overview - Internet website: http://www.sonatasleep.com (printed Mar. 5, 2001).		
DW	Searle Ambien (zolpidem tartrate) - Internet website: http://www.searlehealthnet.com (printed Mar. 5, 2001).		
DX	Healthcare Professionals, Introduction - "Eat Less - The point of change program encourages your patients to do more" - Internet website: http://www.4meridia.com (printed Mar. 5, 2001).		

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		Filing Date: March 5, 2002	Group: 1614
DY	Healthcare Professionals, Mechanism of Action- "Lose weight by eating less"- Internet website: http://www.4meridia.com (printed Mar. 5, 2001).		
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.